



HCCA's 12TH ANNUAL COMPLIANCE INSTITUTE

APRIL 13–16, 2008 | NEW ORLEANS, LA | HILTON RIVERSIDE NEW ORLEANS

P2 - Clinical Laboratory Compliance Outside the Hospital: From the Simple to the Complex and Diverse

Introduction and Speakers



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Objectives

- Understand the broad range of compliance laws and regulations a they apply to clinical laboratories outside the hospital
- Get the latest information on current and upcoming compliance issues relevant to clinical laboratories
- Get answers to your specific laboratory compliance questions



Speakers

- Diana W. Voorhees, MA, CLS, MT, SH, CLCP
Principle/CEO DV & Associates, Inc.
- Christopher Young, CHC, President, Laboratory
Management Support Services
- C. Anne Pontius, MBA, CMPE, MT(ASCP), Senior
Director, Quality Systems, Expression Analysis, Inc.
- Phyllis Schubert, MHS, CHC, MT(ASCP), SH, Director,
Compliance and Regulatory Affairs, Tricore Reference
Laboratories



Presentations

1. Basic Laboratory Compliance (C. Young)
2. Current Issues in Laboratory Coding and Billing (D. Voorhees)
3. Stark and Anti-kickback for Laboratories (C. Young)
4. CLIA and FDA Laboratory Regulations (A. Pontius)
5. HIPAA for Laboratories (P. Schubert)
6. Questions and Answers with discussion (All faculty and the participants)



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Basic Laboratory Compliance

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Clinical Laboratory Compliance

- Laboratory compliance programs consist of the same seven elements as all other compliance programs
- The difference is the risk areas specifically designated for clinical laboratories
- Some of the risks talked about in the 1998 compliance guidance for laboratories either don't exist today or have changed
 - Compliance programs based on the specific risks defined in the 1998 guidance are not targeting the appropriate risks for today's regulatory environment
- Laboratories engaged in research or clinical trials that are in any way reimbursed by the government, may need to include an element for this as well

Laboratory Compliance Is Unique

- First to have compliance guidance published by the OIG
- Laboratories exist in almost every health care setting
 - Laboratory compliance officers must coordinate their compliance programs with the hospital or health system's program
- May not be in a position to affect all decisions related to laboratory compliance processes
- Billing and coding may be done in the hospital billing department
- Relations with physicians may affect other departments who are not aware of the lab's relationship with the same physician
- Inpatient, outpatient and nonpatient (outreach) testing may have different rules



Risk Areas For Today's Laboratories

- Billing and coding but not for the same reasons as existed in 1998
- Sales and marketing and “business development”
- Stark and Anti-kickback issues
- Compliance program effectiveness
- Some of the things cited as risks or activities that laboratories should be engaged in that were included in the 1998 compliance guidance for laboratories are no longer areas of focus because of changes in the ways that laboratories do business or the way that physicians order tests

Risk Areas-Billing and Coding

- Laboratories may be paid under many different payment processes, sometimes more than one apply to the same laboratory
 - Clinical diagnostic laboratory fee schedule
 - Medicare physician fee schedule
 - Hospital outpatient perspective payment system (HOPPS)
 - Inpatient perspective payment (DRG) system
 - Part A/B for Skilled Nursing Facilities (SNF)
 - Charged based payment (Critical Access Hospitals)
 - ESRD payment process (composite and fee for service)
 - Medicare managed care contracts (Part C and Medicare risk based contracts, capitated etc.)

Billing and Coding

- Panels and profiles have changed in CPT
 - Laboratories use fewer customized panels
- Genetic testing is becoming more prevalent
 - Molecular diagnostic coding is complex
- Laboratory Developed Tests (LDTs)
 - FDA intrusion into the laboratory marketplace
- Billing for referral tests
 - Can vary based on type of laboratory or type of patient
 - Independent laboratory versus hospital laboratory
 - Inpatient, outpatient or nonpatient
- Anti-markup provisions for technical component of tests paid on the physician fee schedule

Sales and Marketing/Business Development

- 1998 guidance was primarily concerned with “deceptive” marketing that led to the performance of unnecessary tests
 - Still true but the expansion of the use of LDTs, genetic testing and proprietary testing has introduced an additional layer of concern similar to pharmaceutical companies marketing of “off label” use of drugs
- More extensive partnerships and other kinds of relationships between laboratories and physician owned entities or other players in the laboratory marketplace
- Discounting practices

Stark and Anti-kickback issues

- Since the 1998 guidance was published, there have been several publications of Stark regulations and Advisory Opinions that impact laboratories
- Stark and Anti-kickback concerns for laboratories
 - Phlebotomists in client offices
 - Lease and rental of space or equipment from or to physicians
 - Non-monetary compensation
 - Provision of computers and software
- Competition among laboratories creates risk tolerant environment for some laboratories
- As physician financial situation worsens, they look for more creative ways to increase revenues

Compliance Program Effectiveness

- Few laboratories have been prosecuted for compliance violations in the last few years
 - More difficult to keep administration interested in the laboratory's compliance program
- Laboratories have not updated their compliance plans to accommodate newer risk areas
 - Still looking to the original compliance guidance for risk areas
- Auditing and monitoring programs have not been updated to deal with newer risk areas
- Training and education is still an issue for laboratories
 - Few laboratory specific commercially available training packages

Where To Expend Resources

- Review and update of your compliance program
 - Are policies and procedures current?
 - Are you targeting the current risks areas for your laboratory?
- Review and update of your auditing and monitoring plan
 - Are you looking at the appropriate risk areas for current practice?
- Review and update of your training materials
 - Do the training and education materials reflect current practice?
- What not to focus on:
 - Annual notices to physicians
 - Monitoring utilization of tests

Thank You

Christopher Young, CHC

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Current Events Coding and Billing Issues

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New CPT 2008

- CPT 80047 – Basic metabolic panel (Calcium, ionized) (BMP)
 - *Calcium, ionized* (82330)
 - Carbon dioxide (82374)
 - Chloride (82435)
 - Creatinine (82565)
 - Glucose (82947)
 - Potassium (84132)
 - Sodium (84295)
 - Urea Nitrogen (BUN) (84520)

Ionized Calcium BMP

- Duplicate the 2007 BMP, CPT 80048, except:
Replacement of an ionized calcium in lieu of a total calcium
- Original BMP, CPT 80048, will include (Calcium, total) in parentheses as part of a revised description
- Accommodates POC instrumentation
 - Kidney and liver disease
- Report the correct code

Modifiers

- Commonly Indicated for Pathology:
 - -TC Technical Component
 - -26 Professional Component
 - -32 Mandated Services
 - -52 Reduced Services
 - -59 Distinct Procedural Service
 - -90 Reference (Outside) Laboratory
 - -91 Repeat Clinical Diagnostic Laboratory Test

Example Modifier

- CPT 83912-26
 - Professional component only for interpretation of molecular diagnostic assay
 - Medicare reimburse under the MPFS
 - Approximately \$18 – vary by locale
 - -TC does not apply with this code
 - Without a modifier, Medicare reimburse under CLFS
 - \$5.60

CPT 83912-26

- Billed to government payers when the interpretation is rendered by a pathologist
- Relates to CPT codes 83890 through 83914
- Medicare requirements:
 - Requested by attending physician
 - Relate to abnormal or unexpected result
 - Require the expertise of the pathology physician
 - Result in written report that is included in the patient record
 - A standing order may replace the individual request for the interpretation

Correct Coding Initiative (CCI)

- Column 1/Column 2 Edits
 - One reported code considered an integral part of another reported code
 - Payment is realized for only the column one code
 - Ex: CPT 83912 Molecular diagnostics; interpretation and report
 - CPT 80500 Clinical pathology consultation; limited, without review of patient's history and medical records
 - CPT 83912 reimbursed; 80500 bundled

Correct Coding Initiative

- Significant October Changes - FNA
 - CPT 88104 (fluid slides) not with 88172 (eval) or 88173 (process/interpretation)
 - CPT 88107 (filter) not with 88173
 - CPT 88160 and 88162 (slides not fluid) not with 88173
 - CPT 88112 (LBP) not with 88173

Medically Unlikely Edits (MUEs)

- Transmittal 155 (8/4/06)
- “...excess charges due to units of service greater than the MUE may not be billed to the beneficiary (this is the “provider’s liability”), and this provision can neither be waived nor subject to an advanced beneficiary notice (ABN)”

Medically Unlikely Edits (MUEs)

- Claims Processing
 - Hospital files a claim through an intermediary
 - MUE is exceeded for one line of service
 - Entire claim will be returned to the provider
 - The good news is that the claim may be corrected (changed) and refilled. While accounts receivable will be delayed, there is not an automatic denial for the first claim.

Medically Unlikely Edits (MUEs)

- Claims Processing
 - Carrier receives a claim and the MUEs are exceeded for one line of service
 - Entire line will result in denial
 - Ex: MUE may be associated with a cap of 4 units. If 10 units are billed, all ten units will be denied. Payment will not be processed for the first 4 units
 - No allowance for a patient waiver; ABNs not applicable
 - All 10 units become the liability of the provider.

Array Codes

- *CPT* *Description*
- 88384 Array-based evaluation of multiple molecular probes; 11 through 50 probes
- 88385 51 through 250 probes
- 88386 251 through 500 probes

Array Codes

- Typically surgical and cytopathology techniques employed
- Preparation (TC) defers to molecular diagnostic codes 83890 – 83892, 83898 – 83901
- If a genetic locus is analyzed multiple times, it should only be counted once
- Less than 11 probes, defer to 83890 - 83914

Array Codes

- PC includes much more than an interpretation of results
 - Include any pathologist review of patient information/slides that determines gene dosage and warrants continuing the procedure
 - Review of controls for appropriate results, verifying patient results, and providing both analytical and clinical interpretation

Array Codes

- *CPT Assistant*
 - Current array code set “is to be used only for array-based analyses that include pathologist interpretation”

Medicaid Coverage Rules

- Example for one agency
 - Only one unit of a CPT code is allowed for payment. All units in excess of one are denied
 - Only exceptions are CF testing and cell markers
 - Simulates state incorporation of MUEs
 - TC modifier is required by Medicaid agency to report the technical component only for a service
 - Even in a hospital setting

Medicaid Audit Sample

<i>CPT</i>	<i>Units Billed</i>	<i>Charge</i>	<i>Units Reimb.</i>	<i>Allowable</i>
83891TC	1	\$ 8.90	1	\$ 5.54
83896TC	54	480.60	1	5.54
83895TC	81	720.90	0*	0
83898TC	4	371.20	1	23.17

* Not a code

Medicaid Modifier Usage

- Modifier -91 and -59 not recognized (one agency)
- Modifiers recognized are:
 - -26 Professional component
 - -TC Technical component
 - -ZS Professional and technical components
 - -QW CLIA waived tests
 - -90 Reference (Outside) Laboratory
 - -99 Used when two or more modifiers are necessary to define the procedure

State Regulations

- Example:
 - Direct Billing
 - Performing provider must bill
 - Includes (may not be complete):
 - Arizona California Iowa
 - Louisiana Montana Nevada
 - New Jersey New York South Carolina
 - Rhode Island
 - California bill just extended direct billing to all anatomic pathology (not just cytopathology)

State Regulations, Cont.

- Example:
 - Anti-Markup
 - Billing entity can bill but cannot markup the purchased price
 - Includes approximately 6 states

State Regulations, Cont.

- Example:
 - Disclosure Required for Markup
 - Includes (may not be complete):
 - Tennessee North Carolina Texas (07)
 - Connecticut Delaware Florida
 - Maine Maryland Pennsylvania
 - Texas Vermont Utah (07)

State Regulations, Cont.

- State AG Opinions
 - Washington
 - Minnesota
 - Mark-up might represent fraud
- Some states affect AP only
- Usually exempt IL to IL referrals

Thank you for your courtesy!

Diana



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Stark and Anti-kickback Regulations Applicable to Clinical Laboratories

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Anti-Kickback

- Became law in 1972
 - Violations were a misdemeanor
- Upgraded in 1977
 - Added “solicitation or offer” language
 - Made violation a felony
- 1987 patient protection act
 - Added exclusion authority
 - Required development of “safe harbors”
- Provides criminal penalties for individuals or entities that **knowingly and willfully** offer, pay, solicit or receive remuneration in order to induce business reimbursed under Medicare and Medicaid

Stark For Clinical Laboratories

- The first Stark law was written specifically for clinical laboratories (1989)
 - Became effective January 1992 but final regulations were not published until 1995
 - January 2001 “Phase I” final rule superseded previous 1995 laboratory only regulations
 - Final Stark regulations (Phase III) published September 5, 2007
- Allowed for specific laboratory exceptions
 - Forgiveness of amount owed for laboratory or minor billing errors
 - Furnishing items or supplies used **solely** to collect, transport, process or store specimens for the laboratory
 - Provision of computers, printers or fax machines used **solely** for ordering tests and sending results for the laboratory

Stark

- Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation) **unless an exception applies**
 - Financial relationships can be ownership or compensation arrangement
 - Relationship can be direct or indirect
- Prohibits the entity from filing claims with Medicare (or Medicaid) for those referred services unless an exception applies

Areas of Concern for Laboratories

- Lease and/or rental of space
- Lease and/or rental of equipment
- Placing employees in physician offices
- Provision of supplies
- Placement of computers, printers and fax machines
- Discounts
- Payments for personal services
- Gifts and entertainment provided to physicians or referral sources
- Provision of education or CME
- Professional courtesy

Lease or Rental of Space or Equipment

- Patient service stations or testing equipment
- Written agreement, signed by parties, specifying the premises covered
- Term not less than one year
 - Stark-if termed earlier cannot enter a new agreement for the original term
- The rent is set in advance, is at FMV and does not take into account value or volume of referrals
- Space is reasonable for the intended purpose
- Equipment is actually used by the laboratory
- Commercially reasonable even if no referrals

Placing Phlebotomists In a Physician Office

- 1994 Fraud Alert allows this as long as the phlebotomist only performs tasks related to the laboratory
- Stark defers to the Fraud Alert saying that as long as the phlebotomist does only laboratory related tasks
- If the laboratory pays rent for the space the phlebotomist uses, the Stark rental of space exception must be met
- Commercially reasonable means that the phlebotomist should meet the same business criteria that any other phlebotomist employed by the lab meets
 - Number of draws a day that is needed to justify placement
 - Generally, not in close proximity to another phlebotomy station the laboratory operates

Provision of Supplies, Computers and Printers

- The provision of free services and supplies for specimen collection, processing, transporting and storing is allowed
 - Stark specifically prohibits provision of sterile or other gloves and other “fungible, general purpose supplies”
- Stark says the laboratory or physician should be ready to demonstrate that the supplies were furnished based on a community standard and describe the standard
- Printers must be for printing laboratory test results only
 - If connected to a computer, may be used to print laboratory orders
- Computers must also be used for ordering tests or printing results only
 - The laboratory should make the computers immune to other use

Non-Monetary Compensation

- Any free item, entertainment or service given to a physician is remuneration and must meet a Stark exception or Anti-kickback safe harbor
- Stark non-monetary compensation exception allows a laboratory to give up to \$338.00 each CY to referring physicians
 - Per physician, not per group or office
- The item, entertainment or service may not be given in exchange for referrals (AKS)
- The Government expects the laboratory to monitor this
- If the \$338.00 is exceeded the physician cannot make referrals and the laboratory cannot submit claims

Other Stark and Anti-Kickback Issues

- May contract with physicians for certain “personal service” arrangements if criteria is met
- Discounts may be given to physicians or other referral sources as long as they are not connected to referrals that are not covered by the discount
- Laboratories may not give professional courtesy to its physicians or referral sources because the 1994 Fraud Alert specifically prohibits it
- The laboratory may not provide free educational programs to its physicians or referral sources if the program is beneficial to the physician
- Upcoming Physician Quality Reporting Initiative (PQRI) could be a problem for labs if they provide information for free the allows the physician to get increased payments

Thank You

Christopher Young, CHC

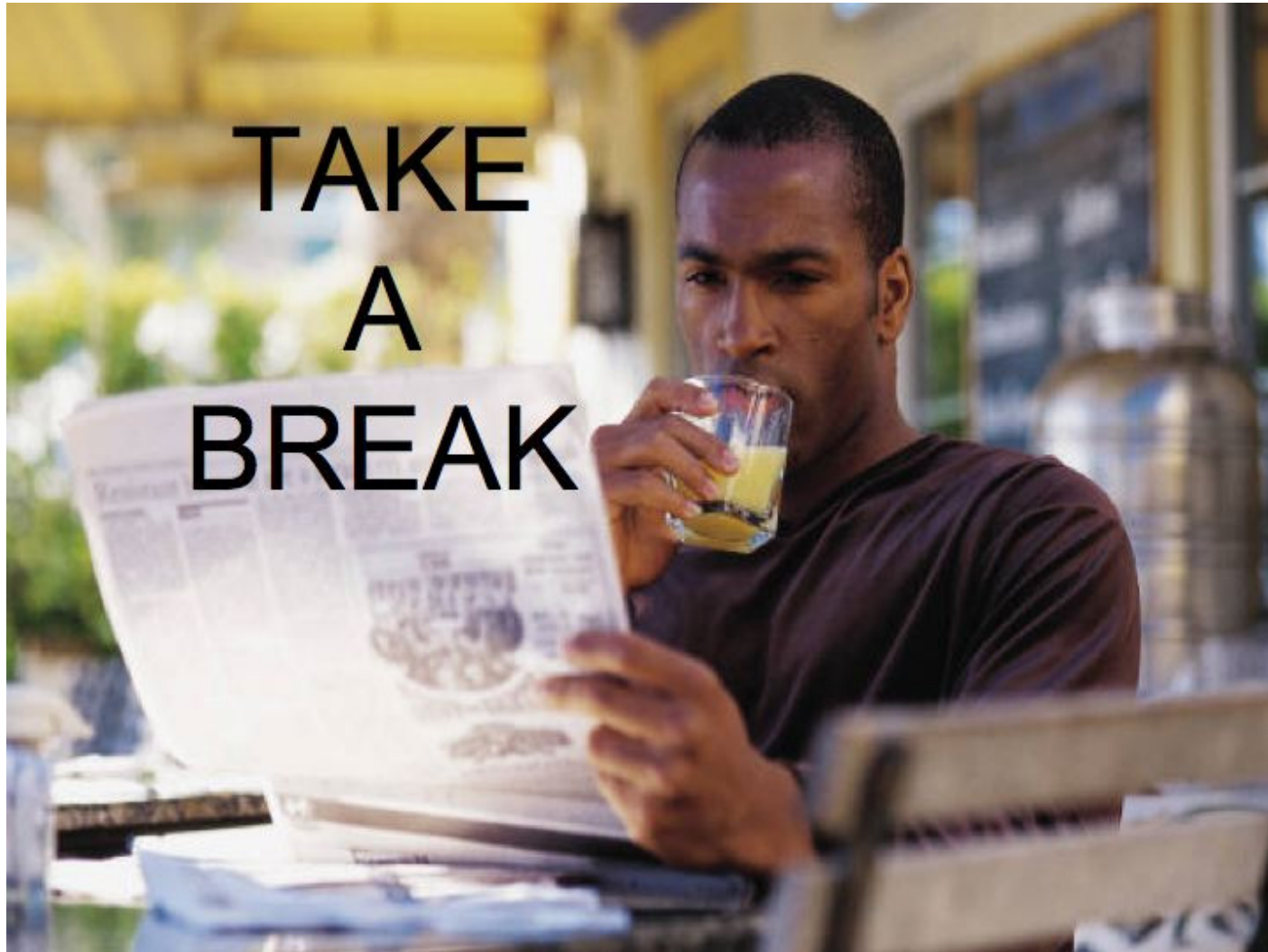
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15 Minutes Please





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Laboratories on the Cutting Edge Research to Clinical

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Expression Analysis, Inc.

- ◆ Genomic Testing Services Provider since 2001
- ◆ Located in Durham, North Carolina
- ◆ Infrastructure built to support clinical trials
- ◆ High throughput microarray processing facility
- ◆ Services include
 - ◆ Multiple platforms for gene expression profiling & genotyping (Affymetrix, Applied Biosystems TaqMan, Illumina, and Luminex)
 - ◆ Statistical data analysis
 - ◆ Experiment design consultations
- ◆ Meets applicable GLP and CLIA requirements

Laboratories Involved in Research

- Clinical Laboratory Improvement Amendments of 1988 (CLIA) – regulated by Centers for Medicare and Medicaid Services (CMS)
- Good Laboratory Practices (GLP) – regulated by Food and Drug Administration (FDA)
- Good Clinical Practices (GCP) Quality Systems – regulated by FDA
- Quality Systems – standards developed by Clinical and Laboratory Standards Institutes (CLSI)

CLIA §493.3: Applicability

- (a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it-- (1) Has a current, unrevoked or unsuspended certificate of waiver, a registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or (2) Is CLIA-exempt.
- (b) *Exception.* These rules do not apply to components or functions of
 - (2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients....

CLIA Background

- All tests fit into a complexity level
 - Waived
 - Moderate
 - High
- FDA searchable database:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>
- Personnel requirements differentiate between Moderate and High complexity tests

CLIA Background

- All clinical laboratories fit into a certificate type
 - Certificate of Waiver
 - Certificate for Provider Performed Microscopy Procedures (PPMP)
 - Registration Certificate
 - Certificate of Compliance
 - Moderate and High complexity testing
 - Certificate of Accreditation

CLIA Compliance

- Laboratories must comply with rules for:
 - Certification
 - Enrollment in proficiency testing (if applicable)
 - Personnel qualifications and responsibilities
 - Facility administration
 - Documentation requirements and retention
 - Facility layout (uni-directional workflow)
 - Quality systems including quality control for:
 - Preanalytic, analytic, and post-analytic processes
 - Inspections

CLIA Inspections

- Every two years on-site
- CMS has authority to close down a testing facility if they suspect harm to patients (immediate jeopardy)

CLIA Personnel Requirements

- CLIA 493.1351 through 493.1495
 - Subpart M
 - <http://www.cms.hhs.gov/CLIA/downloads/apcsubm.pdf>

CLIA Personnel Requirements

		CLIA Certificate→	Waived	PPMP	Compliance	
Title ↓	Testing→	Waived	PPMP	Moderate	High	
Laboratory Director		X	X	X	X	
Clinical Consultant				X	X	
Technical Supervisor					X	
Technical Consultant				X		
General Supervisor					X	
Testing personnel			X	X	X	
Total Roles		1	2	4	5	

Laboratory Director

- Limited to five laboratories
- May delegate certain LD responsibilities to the Technical Consultant, Technical Supervisor or Clinical Consultant
- May serve in the role of the Technical Consultant, Technical Supervisor, Clinical Consultant or Testing personnel if he/she meets qualifications and performs responsibilities

Laboratory Director: Interpretive Guidelines

- *The requirement that a laboratory must be under the direction of a qualified person is not automatically met simply because the director meets the education and experience requirements. It must be demonstrated that the individual is, in fact, providing effective direction over the operation of the laboratory.*

CLIA Quality Systems for Nonwaived Tests

- Specimen Testing Processes - Comprehensive SOPs
- Quality assessment activities
- Pre-analytic
 - Requisition design
 - Capture patient and physician demographic information
 - Reflex testing
 - Components of bundled test
 - Specimen handling procedures
 - Unique specimen identification
- Analytic
 - Quality control
 - Controls must monitor the accuracy and precision of the “complete” analytical process environmental conditions, analytical, operators
 - Material type, frequency, expected results
 - Actions for unacceptable results
 - Maintenance records
 - Documentation for testing records
 - Test performed, who performed it, when it was performed
- Post-analytic
 - Test result report
 - Test result and units of measure
 - Specimen identification

FDA in Clinical Laboratories

- Laboratory Developed Tests (LDTs)
 - Assays developed by the laboratory, which are for internal use and are not sold to outside entities
- Analyte Specific Reagents (ASRs)
 - Components of kits used to produce a test result
 - Sold only to high complexity laboratories
- Intention is to “exercise enforcement discretion” with respect to postmarket QS regulation enforcement for laboratories that manufacture IVDMIAs until the Agency issues QS guidance for such laboratories.

FDA in Clinical Laboratories

An IVD MIA (In Vitro Diagnostic Multivariate Index Assays) is a device that:

- 1) Combines the values of multiple variables using an interpretation function to yield a single, patient-specific result (e.g., a “classification,” “score,” “index,” etc.), that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, and
- 2) Provides a result whose derivation is non-transparent and cannot be independently derived or verified by the end user.

FDA and IVDMIA

- During the investigational period of establishing the safety and performance characteristics of an IVDMIA, it must be labeled,
 - "For Investigational Use Only. The performance characteristics of this product have not been established."

Paul N. Valenstein, MD, FCAP

8 Key Quality Indicators

- 1. Patient Identification
- 2. Blood Culture Contamination
- 3. Critical Value Reporting
- 4. Order Accuracy
- 5. Stat Test Turnaround Time
- 6. Specimen Acceptability
- 7. Anatomic Pathology Discrepancies
- 8. Blood Product Wastage

GOOD LABORATORY PRACTICE

- FOR NON-CLINICAL LABORATORY STUDIES (21 CFR-PART 58)
- Subpart A--General Provisions
- Sec. 58.1 Scope.
- (a) This part prescribes good laboratory practices for conducting **nonclinical** laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections....

Good Laboratory Practices

- The GLP Principles in their strict, regulatory sense apply only to such studies on pharmaceuticals which:
 - Are non-clinical, i.e. are mostly conducted in animals or in vitro, and include analytical aspects.
 - Are conceived to obtain data on the properties and/or safety with respect to human health and/or the environment of the tested substances.
 - Are intended to be submitted to a national registration authority for the purposes of registering or licensing the tested substance or any product derived from it.
 - In general, and depending on national legal requirements, the GLP requirements for non-clinical laboratory studies conducted for safety evaluation in the field of drug safety testing cover the following classes of studies :

Elements of GLP

- Standard Operating Procedures (SOP's).
- Analyst training
- Instrumentation validation
- Reagent/materials qualification
- Statistical procedures for data evaluation
- Specimen/Sample tracking – Chain of Custody

Document Management and Control


- Standard Operating Procedures (SOPs)
 - Quality System Nomenclature
 - Standardized formats
 - General policies and procedures
 - Test Records
 - Document Control
 - On-site – location controlled
 - Limited personnel access
 - Security key card access only
 - Sign in/out all documents
 - Off-site
 - Iron Mountain - barcode controlled and labeled

SOP Nomenclature

QAS_01_0001_Document Nomenclature.pdf - Adobe Reader

File Edit View Document Tools Window Help

8 / 8 116% Find



EXPRESSION ANALYSIS
STANDARD OPERATING PROCEDURES

ID: QAS_01_0001 **MASTER**

Title: Document Nomenclature

Current Effective Date: 19-Dec-07

Status: Active

Appendix 1: Policy and Procedure Format

TITLE:	To be completed by Quality Systems (QS) personnel
DOCUMENT ID:	To be completed by QS personnel
EFFECTIVE DATE:	To be completed by QS personnel
WRITTEN BY:	Place author's name here
STATUS:	To be completed by QS personnel

I) Approvals (QS Personnel will insert titles/names of approvers)

Title:	Printed Name	Signature	Date

II) Cross Referenced Policies and Procedures (insert all documents that are cross referenced)

Document Identification	Title

III) References

A) List all associated references (external to EA).

IV) Revisions (QS personnel will insert appropriate information)

Revision number	Current Effective Date	Revision Summary
01		

V) Purpose:

A) State the reason for this document. As closely as possible, complete the following: The purpose of this policy is to ...

VI) Scope

A) State the breath of the document in terms of tasks and individuals. As closely as possible complete the following: The scope of this document extends to ...

VII) Policy

A) State the overall intentions and directions defined by EA's leadership and answer the question "What do we do at EA?" As closely as possible complete the following: It is the policy at EA that ...

GLP vs CLIA

- GLP is for non-clinical trials and is enforced by the FDA.
- CLIA is applicable to clinical laboratory tests that are reported to clinicians and patients for the purposes of diagnosing, treating or monitoring a health condition and is enforced by CMS (Centers for Medicare and Medicaid Services).
- The 'laboratory' receives CLIA certification.
- Compliance with the CLIA regulations is based on the adherence to rules applicable to the specific test being performed in the laboratory.
- The laboratory is issued the certificate but the rules apply to the particular test being performed ... in other words a laboratory that is CLIA certified may not be applying CLIA rules to the tests it performs. This is the reality of genomic testing facilities.

EA's Quality System Program

- Laboratory Safety
- Personnel
- Specimen collection, handling, and accessioning
- Proficiency performance evaluations
- Quality control activities
- Facility administration
- Specimen test management
- Reporting specimen test results
- Documentation and record retention
- Quality assessment activities
- Communications and meetings

Quality Assessments

- Equipment IQ/OQ/PQ
- Environmental monitoring
- Kit / reagent validations
- Quality control results
- Specimen results
- Data transfer verifications
- Test results correlate with clinical presentation
- Personnel records
- Incident reports
- Facility security logs
- Information system updates / versions
- On and off site documentation storage

Implement corrective / preventive actions based on assessment outcomes.

Thank You

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GET YOUR DOCUMENTATION READY: How to Respond to the Office of Civil Rights on a HIPAA Violation

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HIPAA-Health Insurance Portability and Accountability Act – Privacy Rule

- Protection of rights of patients to their own information
- Protection of the information from unauthorized disclosure outside of:
 - Treatment
 - Payment
 - Operations
- Examples:
 - Taking patient demographic information quietly
 - Patient sign-in sheets



HIPAA-Health Insurance Portability and Accountability Act – Security Rule

- Protection of individually identifiable health information in our care
 - that we created, received or maintained
 - at rest or transmitted
 - in electronic form: ePHI
- Examples:
 - Transmission of ePHI over the internet without authority
 - Allowing someone else to use your password or user name
 - Unshielded monitors with ePHI



What does HIPAA Privacy mean to providers?

- Gives patients more control over their PHI
- Sets boundaries on how PHI is used and released
- Establishes safeguards
- Holds violators accountable
- Strikes a balance between public responsibility for disclosure and need to respect patient privacy
- For example: to protect public health



What does HIPAA Privacy mean to patients?

- Gives patients more control over their PHI
- Empowers patients to know how their PHI is used and disclosed
- Limits release of PHI to the minimum necessary except for treatment (without written authorization)
- Right to a copy of their results and to request correction
- Allows patients to control some uses and disclosures of their PHI.



Prevention of a HIPAA Privacy Violation

- Notification of patients rights
 - Notice of privacy practices for PHI
 - “This notice describes how medical information about you may be used and disclosed and how you can get a access to this information. Please review it carefully.”
- Established policies and procedures
 - Training employees
 - Designating a responsible person as the Privacy Officer
- Securing PHI to be used only by those needing the information for TPO

How do patients complain to OCR?



- Privacy Officer of covered entity
 - Patient or provider should lodge complaint first with covered entity
- US DHHS OCR
 - All complaints must be in writing, either electronically or on paper

www.hhs.gov/ocr/privacyhowtofile.htm

Notification from Office of Civil Rights – Regional Offices

- The first notification that you have had a violation reported may come by:
 - phone
 - letter
 - both
- When contacted by the OCR, be prepared to:
 - admit
 - deny
 - state that you do not know but will investigate

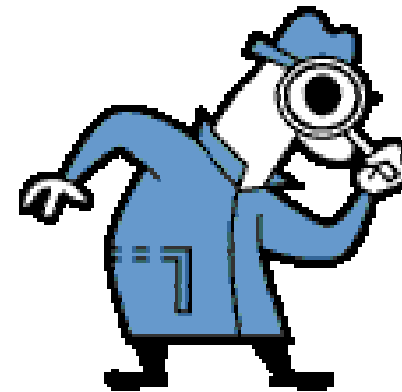


HIPAA COMPLAINT

- Complaint must name a person and describe the acts
- Complaint must be within 180 days of alleged offense
- Covered entity must submit the reports and records to the investigator
- Covered entity must cooperate with the investigation
- If complaint resolved by informal means:
 - OCR will inform the covered entity in writing
 - OCR will inform the complainant in writing
- If no violation occurred, OCR will also inform the parties in writing

Documents of your original investigation

- Documentation of your original investigation should include:
 - your notes from when you first learned of the violation
 - dates and times you interviewed personnel in investigating the allegation
 - your findings in the allegation



Mitigation of the damages

- If the allegation proved to be true after your initial investigation, what steps did you take to mitigate the circumstances:
 - Did you apologize? If you are not at fault, you could still apologize that the situation occurred at all.
 - Did you take responsibility on behalf of your organization?

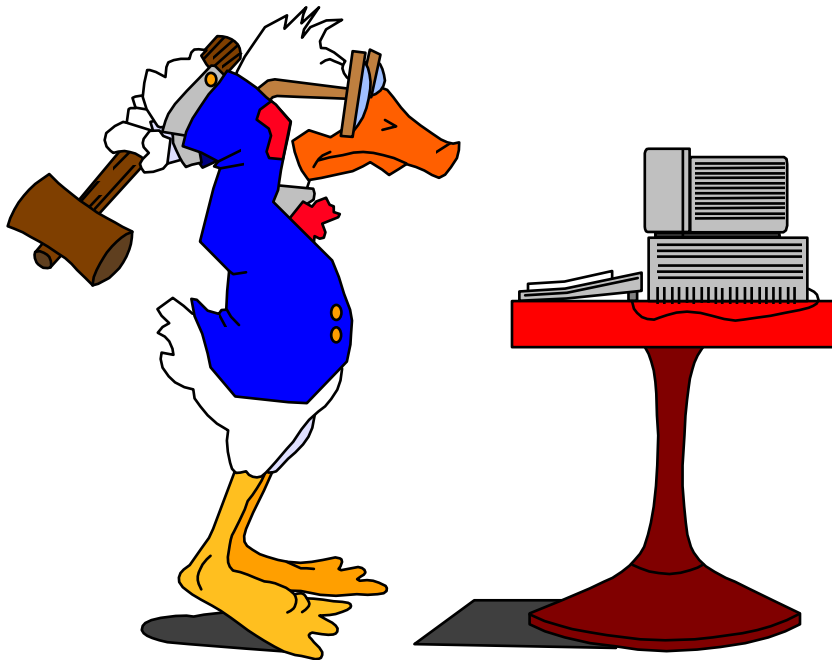
Safeguard to prevent recurrence

- Was there adequate HIPAA privacy training for the offending employee?
- Did re-training take place?
- Did you put a system control in place to prevent this from happening again?
- Was there a change in policy as a result of this breach in confidentiality?

Reassurance to the OCR

- What assurance can you give to the OCR that a similar circumstance will not recur?
- Tip: approach as if you were going to court and had to plead your case. Show as much evidence as possible to support your claim or position.
- You will get a copy of the closure letter to the complainant from the OCR if your investigation documentation was adequate.

NO DESTRUCTION OF RECORDS – NO RETALIATION



- You must follow your stated retention of records policies
- A covered entity may not threaten, intimidate, coerce, harass, or take any retaliation against a complainant for:
 - Filing a complaint
 - Testifying
 - Opposing any action

CIVIL MONETARY PENALTIES

If covered entity has violated an HIPAA administrative simplification provision:



- CMP can be assessed to an individual, group, or to each member of the group
- The covered entity is responsible for the CMP for any member of their workforce
- Amount: not less than \$100 per violation, not more than \$25,000 in aggregate for identical violations during a calendar year

Thank You

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Audience Questions and Discussion



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